

unless it is listed as required in subpart C of this part and manufactured, prepared, propagated, compounded, or processed at a registered foreign drug establishment; however, this restriction does not apply to a drug imported or offered for import under the investigational use provisions in part 312 of this chapter, or the investigational new animal drug use provisions in part 511 of this chapter, or to a component of a drug imported under section 801(d)(3) of the act. Foreign drug establishments shall submit all listing information, including labels and labeling, and registration information in the English language.

(c) Each foreign drug establishment required to register under paragraph (a) of this section shall submit the name, address, and phone number of its United States agent as part of its initial and updated registration information in accordance with subpart C of this part. Each foreign drug establishment shall designate only one United States agent.

(1) The United States agent shall reside or maintain a place of business in the United States.

(2) Upon request from FDA, the United States agent shall assist FDA in communications with the foreign drug establishment, respond to questions concerning the foreign drug establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign drug establishment. If the agency is unable to contact the foreign drug establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign drug establishment.

(3) The foreign drug establishment or the United States agent shall report changes in the United States agent's name, address, or phone number to FDA within 10-business days of the change.

[66 FR 59157, Nov. 27, 2001]

## PART 208—MEDICATION GUIDES FOR PRESCRIPTION DRUG PRODUCTS

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### Subpart A—General Provisions

#### § 208.1 Scope and purpose.

(a) This part sets forth requirements for patient labeling for human prescription drug products, including biological products, that the Food and Drug Administration (FDA) determines pose a serious and significant public health concern requiring distribution of FDA-approved patient information. It applies primarily to human prescription drug products used on an outpatient basis without direct supervision by a health professional. This part shall apply to new prescriptions and refill prescriptions.

(b) The purpose of patient labeling for human prescription drug products required under this part is to provide information when the FDA determines in writing that it is necessary to patients' safe and effective use of drug products.

(c) Patient labeling will be required if the FDA determines that one or more of the following circumstances exists:

(1) The drug product is one for which patient labeling could help prevent serious adverse effects.

(2) The drug product is one that has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect patients' decision

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to use, or to continue to use, the product.

(3) The drug product is important to health and patient adherence to directions for use is crucial to the drug's effectiveness.

#### § 208.3 Definitions.

For the purposes of this part, the following definitions shall apply:

(a) *Authorized dispenser* means an individual licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to provide drug products on prescription in the course of professional practice.

(b) *Dispense to patients* means the act of delivering a prescription drug product to a patient or an agent of the patient either:

(1) By a licensed practitioner or an agent of a licensed practitioner, either directly or indirectly, for self-administration by the patient, or the patient's agent, or outside the licensed practitioner's direct supervision; or

(2) By an authorized dispenser or an agent of an authorized dispenser under a lawful prescription of a licensed practitioner.

(c) *Distribute* means the act of delivering, other than by dispensing, a drug product to any person.

(d) *Distributor* means a person who distributes a drug product.

(e) *Drug product* means a finished dosage form, e.g., tablet, capsule, or solution, that contains an active drug ingredient, generally, but not necessarily, in association with inactive ingredients. For purposes of this part, drug product also means biological product within the meaning of section 351(a) of the Public Health Service Act.

(f) *Licensed practitioner* means an individual licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to prescribe drug products in the course of professional practice.

(g) *Manufacturer* means for a drug product that is not also a biological product, both the manufacturer as described in § 201.1 and the applicant as described in § 314.3(b) of this chapter, and for a drug product that is also a biological product, the manufacturer as described in § 600.3(t) of this chapter.

(h) *Medication Guide* means FDA-approved patient labeling conforming to the specifications set forth in this part and other applicable regulations.

(i) *Packer* means a person who packages a drug product.

(j) *Patient* means any individual with respect to whom a drug product is intended to be, or has been, used.

(k) *Serious risk or serious adverse effect* means an adverse drug experience, or the risk of such an experience, as that term is defined in §§ 310.305, 312.32, 314.80, and 600.80 of this chapter.

### Subpart B—General Requirements for a Medication Guide

#### § 208.20 Content and format of a Medication Guide.

(a) A Medication Guide shall meet all of the following conditions:

(1) The Medication Guide shall be written in English, in nontechnical, understandable language, and shall not be promotional in tone or content.

(2) The Medication Guide shall be scientifically accurate and shall be based on, and shall not conflict with, the approved professional labeling for the drug product under § 201.57 of this chapter, but the language of the Medication Guide need not be identical to the sections of approved labeling to which it corresponds.

(3) The Medication Guide shall be specific and comprehensive.

(4) The letter height or type size shall be no smaller than 10 points (1 point = 0.0138 inches) for all sections of the Medication Guide, except the manufacturer's name and address and the revision date.

(5) The Medication Guide shall be legible and clearly presented. Where appropriate, the Medication Guide shall also use boxes, bold or underlined print, or other highlighting techniques to emphasize specific portions of the text.

(6) The words "Medication Guide" shall appear prominently at the top of the first page of a Medication Guide. The verbatim statement "This Medication Guide has been approved by the U.S. Food and Drug Administration" shall appear at the bottom of a Medication Guide.